## Remarks

The present invention is directed to kits for intravesicular instillation of resiniferatoxin, tinyatoxin, 20-homovanillyl-mezerein or 20-homovanillyl-12-deoxyphorbol-13-phenylacetate. Claims 1-3 and 5-10 are pending. Claim 3 has been amended. Claim 4 has been previously cancelled. By entry of this amendment, claims 1-3 and 5-10 are pending.

### Claim Objections

Claim 3 stands objected because the term "powder" was misspelled. Applicants have amended claim 3 to correct this typographical error and therefore request withdrawal of this objection.

### Rejections under 35 U.S.C. §102

Claims 1, 5 and 6-7 have been rejected under 35 U.S.C. §102(b) for lacking novelty over Craft et al, Physiology & Behavior 56(3):479-486, 1994 ("Craft"). Applicants respectfully traverse the rejection.

The Examiner erroneously quotes Craft at page 80 and mischaracterizes the teachings of the prior art. As such, the Examiner's calculation of RTX is incorrect. The correct quote from Craft should read as follows:

> "Resiniferatoxin (Chemicals for Cancer Research, Inc., Edina, MN) was dissolved in ethanol to which Tween-80 and saline were added; final solutions contained ≤2% ethanol and 1% Tween-80." *Drugs* p. 480

Applicants respectfully note that the final composition (of the solution of RTX, saline and Tween-80) contains ≤2% ethanol and 1% Tween-80. There is no teaching of the concentration of RTX stock ethanol solution in Craft. The only concentrations provided are for the administration doses, which are between 0 and 10 nmol, and which are below the claimed range of RTX. Therefore Craft does not disclose the claimed range of RTX and fails to anticipate the claimed kit. Withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. §103**

Claims 2 and 3 have been rejected under 35 U.S.C. §103 for being obvious over Craft in view of U.S. Patent No. 4,939,149 ("Blumberg"). Applicants respectfully traverse the rejection as it applies to the amended claims.

Craft is discussed above. Blumberg fails to disclose the claimed concentration ranges. Again, the Examiner's characterization of the prior art is incorrect. At column 5, lines 25-40, Blumberg does not refer to RTX present in a composition between 0.0001 to 10% by weight of the individual. Blumberg specifically states "In terms of composition, compounds should be present between 0.0001 to 10% by weight". (emphasis added). Blumberg refers to the *composition*, not the *individual's weight*. Even still, the six order of magnitude dosage range disclosed above is not useful for one of ordinary skill and would require undue experimentation to arrive at the claimed ranges absent the teachings of the present specification.

Blumberg teaches that resiniferatoxin is an extremely irritant diterpene with an effective dose between 2-20 μg/kg. (column 4, lines 27-45). Even the examples of the specification necessitate the use of ether anaesthesia to avoid unnecessary pain (column 6, line 34). One of ordinary skill would conclude, when faced with the teachings of Blumberg, that RTX would cause pain and burning sensations when administered. Blumberg actually teaches away from the Applicants' invention that low doses of RTX in humans treats urinary incontinence without causing pain or burning sensations that are associated with CAP treatment or higher concentrations of RTX that are seen in Blumberg. (Specification paragraphs 14). The claimed kit is inventive by providing a dosage that treats urinary incontinence without pain and burning sensations. This feature could not possibly be obvious in view of the teachings of Blumberg that teach how irritating RTX is. Even Craft teaches that RTX administration in rats results in a visceral nociceptive response. (Craft, page 479, second column). As such, neither Craft or Blumberg provides sufficient motivation to arrive at the claimed kits for providing a therapeutic dosage of RTX as claimed and fail to render the claimed kits obvious. Withdrawal of this rejection is respectfully requested.

Claims 8-10 have been rejected under 35 U.S.C. §103 for being obvious over Craft in view of U.S. Patent No. 2,182,075 ("Ebert"). Applicants respectfully traverse the rejection as it applies to the amended claims

Craft has been discussed above. Ebert fails to make up for the deficiencies of Craft and therefore fails to render the claimed kits obvious. Withdrawal of this rejection is respectfully requested.

**Double Patenting**

Claims 1-3 have been rejected for obviousness-type double patenting over U.S. Patent 6,630,515. Applicants request deferral of this rejection until such a time that patentable subject matter is found. At that time, Applicants will file an appropriate terminal disclaimer if necessary.

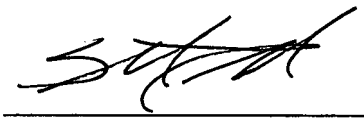
**Conclusions**

Applicants submit that the response herein provides a complete response to the Office Action dated April 5, 2007.

If the Examiner believes there are other issues that may be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned is respectfully solicited.

No additional fees are believed due, however the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment of fees to Deposit Account number 11-0980.

Respectfully submitted,



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